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#22

In re Application of	:
JANNES et al.	:Renewed Petition to Review Lack of Unity
Serial No: 09/787,000	:Under 37 C.F.R. 1.144
Filed: 13 March 2001	:
Attorney Docket No: 2551-58	:

This is in response to applicant's petition under 37 CFR 1.144, filed 23 October 2003, requesting renewed review of the Examiner's lack of unity requirement mailed 22 May 2002 and the petition decision mailed 23 September 2003. The delay in acting on this petition is regretted.

BACKGROUND

This application is a U.S. national stage application properly filed under 35 USC 371. The application history was reviewed in the petition decision mailed 23 September 2003. This petition was filed 23 October 2003, concurrent with the filing of Supplemental Amendment C, which added new claims 30-49. On 8 January 2004, applicants filed a Supplemental Amendment C, which added amended claims 13, 17 and 36. In their remarks, applicants mention an interview with Examiner Foley and SPE Housel, however no interview summary is of record in the file.

RELEVANT AUTHORITY

An international or a national stage application are considered to have unity of invention where there exists a "special technical feature" that defines a contribution which each of the claimed inventions, considered as a whole, makes over the prior art. See PCT Rule 13.2; 37 CFR 1.475(a), (b)(1) and (2).

PCT 13.2 Circumstances in Which the Requirement of Unity of Invention Is to Be Considered Fulfilled

Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or

corresponding special technical features. The expression “special technical features” shall mean those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art.

See MPEP 1893.03(d) and Annex B, Part 2 of the PCT Administration Instructions

Unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims and

(i) If the independent claims avoid the prior art and satisfy the requirement of unity of invention, no problem of lack of unity arises in respect of any claims that depend on the independent claims;

(ii) If however, an independent claim does not avoid the prior art, then the question whether there is still an inventive link between all the claims dependent on the claim need to be carefully considered. If there is no link remaining an objection of lack of unity a posteriori (that is, arising only after assessment of the prior art) may be raised. See ANNEX B: Unity of Invention Part 1 “Instructions Concerning Unity of Invention” MPEP AI-6 (Rev. 1. Feb. 2003).

Regarding the determination of a “special technical feature” under Rule 13.2 when dealing with “Markush Practice”, MPEP: Annex B “Unity of Invention Part 1 Instructions Concerning Unity of Invention” and “Part 2 Examples Concerning Unity of Invention” is instructive.

In accordance with Annex B (f) “Markush Practice”, the requirement of a technical interrelationship and the same or corresponding special technical feature as defined in Rule 13.2, shall be considered to be met when the alternatives are of a “similar nature” which occurs when the following criteria are fulfilled:

(A) all alternatives have a common property or activity, and

(B)(1) a common structure is present, i.e. a significant structural element is shared by all of the alternatives, or

(B)(2) in cases where the common structure cannot be the unifying criteria, all alternatives belong to a “recognized class of chemical compounds” in the art to which the invention pertains.

DISCUSSION

Applicant’s renewed petition, amended claims and the file record have been carefully considered.

In view of the amendment filed 8 January 2004, claims 13-49 correspond to the following groups as follows:

Group I, claims 13-36 drawn to a method of detecting acute respiratory tract infection using a

mixture of primer sets including one from each of the following 5 viral genes:
the F1 subunit of the fusion glycoprotein gene of RSV,
the hemmagglutininneuraminidase gene of PIV-1,
the 5' non-coding region of the PIV-3 fusion protein gene,
the non-structural protein gene of influenza A and
the non-structural protein gene of influenza B.

Group II, Claims 37, 42, 47, drawn to a probe or primer.

Group III, claims 38-41, 44 and 45, drawn to a primer pair.

Group IV, Claims 43, 46, 48 and 49 drawn to the combination of a primer set and a probe.

Each of Groups II, III and IV contain probes, primers, primer pairs or probe and primer combinations which lack unity one with another. Each probe or primer in Group II constitutes one invention. PCT Administrative Instructions, Annex B, Markush Practice, requires that the molecules claims in the alternative share a common property or activity and a common structure. As shown in Table 3, on page 23 of the specification, the probes and primers lack (1) a common property or activity, since they do not bind to the same organism, same gene or the same portion of the gene, and (2) a common structure which is a significant structural element. For example, SEQ ID NO 4 is specific for Enterovirus; SEQ ID NO 5 is specific for Influenza A. A comparison of the structure of the probes in Tables 4 and 5 also shows lack of significant structural element. For these reasons, unity is lacking between the individual probes and primers and the various combinations.

The reasons for the lack of unity between Groups I-IV follows:

Currently amended independent claim 13 is now drawn to a method which requires a mixture of primer sets from each of 5 viral genes:

The F1 subunit of the fusion glycoprotein gene of RSV,
the hemmagglutininneuraminidase gene of PIV-1,
the 5' non-coding region of the PIV-3 fusion protein gene,
the non-structural protein gene of influenza A and
the non-structural protein gene of influenza B.

The method of claim 13 also requires one further primer set selected from one of the further genes selected from the group consisting of

16S rRNA sequence of *M. pneumoniae*,
spacer sequence of *M. pneumoniae*,
16S rRNA sequence of *C. pneumoniae*,
spacer sequence of *C. pneumoniae*,
the 5' noncoding region of enterovirus and
the hexon gene of adenovirus.

Minimally, the method of claim 13 requires 6 sets of primer pairs, 5 directed at the first five required genes and one selected from a group listing 6 other genes in the alternative.

Claims 37-49 are directed to product claims and include claims for a primer set, a probe, a primer, a collection of primer sets, collection of primer sets and probes, and kits thereof. Claims 37-42, 47 are independent claims. PCT Rule 13.2 requires that the inventions share a same or corresponding technical feature in order for unity to be accepted. Each of the independent product claims will be considered in turn with regard to whether they share a same or corresponding technical feature with the elected method invention of Claim 13, the sole independent claim of Group I.

Claim 37 of Group II is directed to a particular primer selected from a large list of primers identified by a given SEQ ID No. This is not commensurate in scope with the method of claim 13, which does not require and is not limited to any particular primer. Furthermore, the method of claim 13 requires a set of primer pairs, while claim 37 requires only one primer.

Claims 42 and 47 of Group II, are directed to a nucleic acid probe. No nucleic acid probe is required for the method of claim 13, thus the products of claim 42 and 47 lack a same or corresponding technical feature with claim 13. For these reasons, the invention of Group II lacks a same or corresponding technical feature with the invention of Group I.

Claim 38 of Group III requires one primer set and sets forth four groups of possible primer sets, each of which are directed to pairs of particular SEQ ID Nos, complements to the SEQ ID No, RNA sequences corresponding to the SEQ ID No and complements to the RNA sequences. The invention of claim 38 does not share a same or corresponding technical feature with the method of claim 13 which requires 6 sets of primers, none of which are limited to a specific structure. For these reasons, the invention of Group III lacks a same or corresponding technical feature with the invention of Group I.

Although unity of invention has to be considered in the first place only in relation to the independent claims in an international application and not the dependent claims, a few of the dependent product claims recite collections of primers or probes and these will now be compared for unity of invention. Claims 39 and 40 of Group III require two or five primer sets, respectively. The method of claim 13 requires 6 primer sets. Thus the invention of Group II lacks a same or corresponding technical feature with the elected invention.

Claim 41 requires at least nine primer sets, however, the primer sets are not limited to the five required by Claim 13 and the method does not require the particular structure recited in Claim 41. Again, no same or corresponding technical feature is shared between the inventions of Group III and the elected invention.

Claim 43, 46, 48 and 49 of Group IV require a particular primer set and a probe. Thus Group IV lacks a same or corresponding technical feature with Group I because (1) Group I does not require a probe and (2) Group I does not require any specific structure.

For these reasons, unity is lacking between the elected invention, Group I, and Groups II, III and IV.

Even if the products and method had been linked with a technical feature, (which they are not) the shared technical feature does not make a contribution over the prior art. The probe and primer of Claim 37 and 42 are anticipated by Jannes et al (WO96/00298, which teaches SEQ ID No 18) and by Fluitt et al, which teaches SEQ ID NO 15 of claim 42.¹

Turning now to the renewed petition, the following 4 deficiencies were pointed out in the previous petition decision:

- (1) the election of March 14, 2002 was complete with regard to primer sets
- (2) the amendment of 24 June 2002 was complete with regard to the election of one set of primer
- (3) the decision failed to indicate where the PCT Rules allowed for separate requirement for one set of primers and a probe within a method and the product groups.
- (4) the amendment filed 10 March 2003 was complete.

Items (1), (2), (3), (4) are moot in view of the new set of amended claims which was responsive to the petition decision and which obviates any need for any need for an election of a specific primer pair or specific probe within the elected invention. Further, concerning item (3), the PCT Administrative Instructions, Annex B, Markush Practice, allows for lack of unity determination between products recited in the alternative, whether in a method claim or a product claim. This is applied above in the reasoning for the restriction to a specific primer or probe or a specific primer pair or a specific combination of primer pair and probe.

The petition's arguments concerning concurrent examination of various groups of sequences are directed to the non-elected groups and do not apply to the elected invention. The Official Gazette Notice was permissive in nature and not a requirement for the examiners. While examiners are permitted to allow up to ten sequences for concurrent examination, they are not required to do so.

The petition argues that unity of invention exists between products and methods of using as set forth in Example 4 of Annex B, of the PCT Administrative Instructions.

Example 4

Claim 1. Use of a family of compounds X as insecticides.

Claim 2, Compound X1 belonging to family X.

Provided X1 has the insecticidal activity and the special technical feature in claim 1 is insecticide use, unity is present.

Example 4 requires a common property or activity and a contribution over the prior art. The instant inventions differ from those in Example 4 in these two aspects. First, the products within

¹ These references were applied in the (vacated) Office action and will be made of record again the next Office action.

Groups II, III and IV do not share a common property or activity, as each probe or primer is specific for a different organism or a different genes or different portions of a gene. Second, the products do not make a contribution over the prior art, in view of Jannes et al (WO96/00298, which teaches SEQ ID No. 18) and by Fluitt et al, which teaches SEQ ID NO 15 of claim 42.

The amendment presents claims which obviates, in part or in whole, arguments in items (1), (2), (3) and (4) of the petition. In view of the new claims, this petition includes a new lack of unity determination which supplies the required PCT reasoning and addresses applicants' arguments, thus fulfilling the concern of item (3).

DECISION

Applicant's petition to withdraw the lack of unity is **GRANTED-IN-PART** for the reasons set forth above.

The application will be forwarded to the Examiner for consideration of Supplemental amendment B and C, filed 23 October 2003 and 8 January 2004 and preparation of a supplemental Office action consistent with this decision.

Any request for consideration must be filed within two (2) months of the mailing date of this decision.

Should there be any questions regarding this decision, please contact Special Program Examiner Julie Burke, by mail addressed to Director, Technology Center 1600, PO BOX 1450, ALEXANDRIA, VA 22313-1450, or by telephone at (571) 272-1600.



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